DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#19

Re: ACEL-IMUNE®
Docket No. 92E-0115

MAY 22 1992

The Honorable Douglas B. Comer
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Comer:

This is in regard to the application for patent term extension for U.S. Patent No. 4,455,297, filed by Takeda Chemical Industries, Ltd., under 35 U.S.C. 156 et seq. The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent extension for ACEL-IMUNE® (Diphtheria and Tetanus toxoids and Acellular Pertussis Vaccine Adsorbed) that appeared in the Federal Register of May 1, 1992 (page 18887). The notice stated:

> "Of this time, 400 days occured during the testing phase of the regulatory review period, while 1,602 days occurred during the approval phase."

It should have stated:

> "Of this time, 434 days occured during the testing phase of the regulatory review period, while 1,568 days occurred during the approval phase."

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Douglas P. Mueller
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